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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,043	10/23/2000	Brita Sjoblom	1103326 0642	9139

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New York, NY 10036-2787

EXAMINER

PULLIAM, AMY E

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 02/10/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/674,043

Applicant(s)

SJOBLOM, BRITA

Examiner

Amy E Pulliam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Amendment A (actually Preliminary Amendment A, received after mailing of the first office action), the Request for Reconsideration and the Letter, all received by the Office on October 25, 2002.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 14 states, "liquid in which polymer is soluble..." However, claims 7 and 9 teach a suspension and an emulsion, respectively. Therefore it is not required that the polymer be soluble, and there is improper antecedent basis for this limitation. Appropriate correction is required.

The claim objections and the other rejections under 35 U.S.C. 112, second paragraph were withdrawn due to the Preliminary Amendment filed by Applicant. However, the problem discussed in the above rejection was not addressed in that amendment, and has therefore been maintained.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 2329124 to Ratwatte.

Ratwatte teaches a method of producing agent forms by dispersing an agent composition in a solution of a coating material in a liquid carrier material and spraying the resultant dispersed mixture to form fine droplets which are frozen, then drying the said frozen particles to produce a plurality of individual solid parties comprising the agent composition coating with the coating material. Ratwatte further teach that the agent material can be a bio-pharmaceutical or another agent, such as a vitamin (abstract).

It is the position of the examiner that the agent composition of Ratwatte reads on applicant's pharmaceutically active substance (1ai). Further, the coating material of Ratwatte reads on applicant's polymer (1aii). Next, the liquid carrier material of Ratwatte reads on applicant's claimed liquid in which the pharmaceutically active substance and polymer are suspended, dissolved, or emulsified (1aiii). Lastly, Ratwatte teaches spraying the above mixture to form droplets, followed by drying the droplets to form solid particles.

Additionally, claims 18 and 19 are also anticipated by Ratwatte. Claims 18 and 19 are product by process claims. According to the MPEP section 2113, "even though product by process claims are limited by and defined by the process, determination of patentability is based

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on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed.Cir. 1985).

First, Ratwatte does not specifically teach (in the available abstract) all of applicant's specifically claimed polymers. However, the reference in its entirety does disclose a number of the polymers claimed by applicant, such as carageenan, alginate, and cellulose polymers (claim 14). It is the position of the examiner that because the reference teaches some of applicant's claimed polymers, the reference suggests the limitations of the instant claims. Therefore, one of ordinary skill in the art would have been motivated to use a well known coating polymer where Ratwatte calls for a "coating material." Additionally, the selection of a known material based on its suitability for its intended use is obvious absent a clear showing of unexpected results attributable to the applicant's specific selection.

Second, Ratwatte does not give specific percentages of the individual components of the composition. However, this is not to say that Ratwatte's composition does not teach applicant's instantly claimed amounts. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat.

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App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Third, Ratwatte does not specify (in the available abstract) all of the specific solvents claimed by applicant. However, the reference, in its entirety, does teach that the carrier can be water (page 6, line 22), which is one of the solvents claimed by Applicant. Additionally, the solvents claimed by applicant are well known solvents in pharmaceutical compositions, and the selection of a known material based on its suitability for its intended use is obvious absent a clear showing of unexpected results attributable to the applicant's specific selection.

Fourth, Ratwatte does not specifically include plasticizers. However, he does state that excipients and additives are permissible in the composition (p 4, l 12). It is the position of the examiner that plasticizers are well known to be included in coating compositions, particularly for the use in microparticle formulations. Furthermore, as stated above, the selection of a known material based on its suitability for its intended use is obvious absent a clear showing of unexpected results attributable to the applicant's specific inclusion and selection.

It is the position of the examiner that the method of making microparticles disclosed by Ratwatte clearly suggests the method of making microparticles which is instantly claimed by applicant. The burden has been shifted to applicant to disclose any differences between the two processes. Furthermore, one of ordinary skill in the art would have been motivated to form pharmaceutical particles based on the teachings of Ratwatte. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

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Applicant's arguments have been fully considered but are not found to be persuasive. Regarding the above rejection, Applicant argues that the reference does not teach the amount of dry material by volume or the amount of polymer. Furthermore, Applicant argues that these specific limitations are essential to the success of the claimed invention. Applicant further points to pages 12-15 of the specification, as support that these specific limitations are essential to the claimed invention. These arguments are not persuasive because there has been no comparative analysis showing that Applicant's claimed invention achieves results different from the invention of the prior art. As stated in the above rejection, the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977). The evidence relied upon by Applicant shows data pertaining only to the product claimed. In order for this data to show any patentable distinction it is necessary that it be compared to the prior art. This comparison should show that based solely on the variables discussed (the dry weight, and the amount of polymer), Applicant's achieve a better result. For these reasons, the above rejection is maintained.

Conclusion

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600